510(k) Summary

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

APR 4 2013

The assigned 510(k) number is: k130765

Submitter ELITech Clinical Systems S.A.S.
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Contact Valérie GOURDON (Email: v.gourdon@elitechgroup.com)

Date of Preparation March 12th, 2013

Purpose of this submission: To obtain clearance for the devices named in this submission for use with testing **LIPASE.** The devices, ELITech Clinical Systems ELICAL 2 and ELITech Clinical Systems ELITROL I and ELITROL II, have been cleared previously for use with testing other constituents. The **LIPASE** constituent has always been present as part of the formulation of the devices; the design and composition of the devices remains the same as it was when cleared previously for uses with testing other analytes. All the other previously cleared analytes remain the same for stability, value assignment procedure, and traceability. K numbers for the previously cleared constituents are k110830, k112029, k122858, k093883, k110780, k102993, k122083, k112029, k100525, k100263 and k102647.

Device names: (Proprietary names) ELITech Clinical Systems ELICAL 2
ELITech Clinical Systems ELITROL I and ELITROL II

Predicate devices: Roche Diagnostics Calibrator for Automated Systems (C.f.a.s) **(k033501)**
Roche Diagnostics Precinorm U/Precipath U **(k041227)**

Device names

1. CALIBRATOR

Trade/proprietary Name: **ELITech Clinical Systems ELICAL 2**
Common or Usual Name: Calibrator, multi-analyte mixture
Device Class Class II
Classification name Calibrator (21 CFR 862.1150)
Product code **JIX**- Calibrator, multi-analyte mixture

Predicate device Roche Diagnostics Calibrator for Automated Systems (C.f.a.s) (K033501)

Device description ELITech Clinical Systems ELICAL 2 is a lyophilized calibrator based on human serum containing constituents to ensure optimal calibration.
ELICAL 2 is prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

Intended Use

ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.

Comparison to Predicate device

	ELITech Clinical Systems Device (ELICAL 2)	Predicate device (Roche Calibrator f.a.s. K033501)
Intended use	ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.	For *in vitro* diagnostic use in the calibration of quantitative Roche methods on Roche clinical chemistry analysers as specified in the value sheets.
Format	Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels	Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels
Level	Single level	Single level
Handling	Carefully open the vial, avoiding the loss of lyophilizate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam.	Carefully open one bottle, avoiding the loss of lyophilizate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.
Traceability	Traceability information is given in the value sheet included in the box.	Traceability of the target value is given in the respective instruction for use of the system reagents.
Stability	Lyophilized: To store at 2-8°C and protected from light until the expiry date *After reconstitution, the stabilities are :* Between 15-25 °C : 8 hours Between 2-8 °C : 2 days Between (-25)-(-15) °C : 4 weeks (when frozen once) *Exceptions :* - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 3 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once)	Lyophilized: Stable at 2-8°C up to expiration date. After reconstitution, the stabilities* are : - 8 hours at 15-25 °C. - 2 days at 2-8 °C. - 4 weeks at Between (-25)-(-15) °C (when frozen once) Exception for bilirubin total & direct - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 3 hours Between 2-8 °C 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once)

	ELITech Clinical Systems Device (ELICAL 2)	Predicate device (Roche Calibrator f.a.s. K033501)
	- Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 6 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)	- Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 6 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)

Traceability: ELITech Clinical Systems ELICAL 2 is traceable to values established using a titrimetric manual method.

Value Assignment: A target value for lipase is set for the production for the new lot of ELICAL 2. The ELITech Clinical Systems ELICAL 2 value for lipase is verified by calibrating the test system using a previously qualified lot of ELICAL 2 and two different approved lot of lipase reagents and then measuring the amount of lipase in the new lot of ELICAL 2. The calibration factor of the control lots systems must be within an acceptance range. The value obtained for lipase must be ±9% of the target value in order for the lot to be accepted.

Device name

2. CONTROLS

Trade/proprietary Name:	**ELITech Clinical Systems ELITROL I and ELITROL II**
Common or Usual Name:	Multi-analyte controls – all kinds
Device Class	Class I, reserved
Classification name	Quality control material (assayed and unassayed). (21 CFR 862.1660)
Product code	**JJY**- Multi-analyte controls – all kinds

Predicate device Roche Diagnostics Precinorm U (K041227)
Roche Diagnostics Precipath U (K041227)

Device description ELITech Clinical Systems ELITROL I and ELITROL II are two level quality control products consisting of lyophilized human serum containing constituents at desired levels.

Elitrol I and Elitrol II are prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

Intended Use ELITech Clinical Systems ELITROL I and ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.

Comparison to Predicate device

	ELITech Clinical Systems Device (ELITROL I / ELITROL II)	Predicate Device (Roche Precinorm U / Precipath U K041227)
Intended use	ELITech Clinical Systems ELITROL I and ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in accuracy control	For *in vitro* diagnostic use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet.

	ELITech Clinical Systems Device (ELITROL I / ELITROL II)	Predicate Device (Roche Precinorm U / Precipath U K041227)
	of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.	
Format	Lyophilized human sera with constituents added as required to obtain desired components levels.	Lyophilized human sera with constituents added as required to obtain desired components levels.
Levels	Two levels	Two levels
Handling	Carefully open the vial, avoiding the loss of lyophilizate, and pipette in exactly 5 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam.	Carefully open the bottle, avoiding the loss of lyophilizate, and pipette in exactly 5 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.
Stability	Lyophilized: To store at 2-8°C and protected from light until the expiry date After reconstitution, the stabilities are : Between 15-25 °C : 12 hours Between 2-8 °C : 5 days Between (-25)-(-15) °C : 4 weeks (when frozen once) *Exceptions:* - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 8 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)	Lyophilized: Stable at 2-8°C up to expiration date. After reconstitution, the stabilities* are : - 12 hours at 15-25 °C. - 5 days at 2-8 °C. - 4 weeks at (-25)-(-15) °C (when frozen once) *Exception for bilirubin total & direct as noted in package insert: - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 8 hours Between 2-8 °C: 24 hours Between (-25)-(-15) °C: 2 weeks (when frozen once)

Traceability: ELITech Clinical Systems ELITROL I and ELITROL II are traceable to values established using a titrimetric manual method.

Value Assignment: A target value for lipase is set for the production for the new lots of ELITROL I and ELITROL II. The ELITech Clinical Systems ELITROL I and ELITROL II values for lipase are verified by calibrating the test system using a previously qualified lot of ELICAL 2 with two different approved lots of lipase test reagents and then measuring the amount of lipase in the new lots of ELITROL I and ELITROL II. The calibration factor of the control lots systems must be within an acceptance range. The values obtained for lipase must be ±9% of the target value in order for the lots to be accepted.

Conclusion	The performance data and other information demonstrate that the safety and effectiveness of these devices versus the predicate devices are not compromised, and that they met all acceptance criteria, demonstrating that the devices are substantially equivalent to their respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 4, 2013

ELITechgroup
Epoch Biosciences
C/O Debra K. Hutson
21720 23rd Drive, SE
BOTHELL WA 98021

Re: K130765
Trade/Device Name: ELITech Clinical Systems ELICAL 2
ELITech Clinical Systems ELITROL 1 and ELITROL 2
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIX, JJY
Dated: March 19, 2013
Received: March 20, 2013

Dear Ms. Hutson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): __k130765_____

Device Name: ELITech Clinical Systems ELICAL 2

Indications for Use:

ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130765

Indications for Use Form

510(k) Number (if known): ___k130765_____

Device Name: ELITech Clinical Systems ELITROL I
ELITech Clinical Systems ELITROL II

Indications for Use:

ELITech Clinical Systems ELITROL I & ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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